

A Pilot Project to Understand Prescribing Practices of Otitis Media with Effusion

By

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## Abstract

Otitis media is one of the most common reasons for pediatric healthcare visits and a common reason for inappropriate prescribing of antibiotics. Otitis media is differentiated into two categories: acute otitis media (AOM) and otitis media with effusion (OME). OME is characterized by reduced tympanic mobility and middle ear effusion without signs of acute inflammation or infection. Approximately 80% of children will have experienced at least one episode of otitis media by their third birthday. The clinical practice guideline for managing otitis media with effusion was updated in 2016. This guideline supports three months of watchful waiting from start of symptoms or date of diagnosis over the use of antibiotics. **Problem:** Providers continue to use antibiotics for the treatment of OME in the presence of published guidelines. **Project Aim:** The purpose of this project was to understand prescribing practices among health care providers in the diagnosis, treatment and management of OME through the use of a descriptive survey. Donabedian's Quality Framework and structure process outcome model guided the project. **Project Method:** A convenience sample of advanced practice registered nurses (APRNs) and physicians from three area suburban urgent cares were surveyed regarding their knowledge of the current guidelines and factors associated with adherence to prescribing practice guidelines. **Results:** The majority of providers recognized a middle ear effusion as a sign of an OME, however, less than half identified all other potential signs of OME. It was also found that a variety of diagnosis codes were used to document an OME or AOM. Recommendations included provider education on inclusion and exclusion criteria for OME diagnosis and using standardized diagnosis codes for AOM and OME in the urgent cares. These results will direct provider education on OME and antibiotic stewardship in the urgent cares.

*Keywords:* Otitis media, OME, antibiotics, prescribing practices, quality improvement

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“Otitis media is the most common disease seen in pediatric practice, a leading cause of healthcare visits, and the most frequent reason children consume antibiotics or undergo surgery” (Marom et al., 2014, para 1). It is estimated 80% of children will have experienced one or more episodes of otitis media by their third birthday. This diagnosis is also a leading reason for antibiotic prescriptions in the primary care setting (Marom et al., 2014). Otitis media is defined as an infective and inflammatory condition of the middle ear that presents with or without acute signs and symptoms (Lee, Flowerdrew, & Delaney, 2009). There are two primary types: acute otitis media (AOM) and otitis media with effusion (OME).

An acute otitis media is characterized by acute symptoms of otalgia, fever, fluid in the middle ear, and acute inflammation caused by bacteria or viruses (Zureishi, Lee, Belfield, Birchall, & Daniel, 2014). AOM symptoms also include a bulging eardrum with poor mobility, and red or yellow discoloration due to pus in the middle ear (Lee et al., 2009). Otitis media with effusion is characterized by a normal positioned or retracted eardrum with reduced mobility and fluid in the middle ear, but shows no signs of acute inflammation or infection (Lee et al., 2009). Symptoms include hearing loss or a feeling of fullness in the ear, but rarely include otalgia (Qureishi et al., 2014). The hearing loss is usually transient and typically resolves spontaneously although it may take months to a year depending on severity.

Although AOM and OME are types of otitis media, they have different treatment recommendations. Unlike acute otitis media, antimicrobial therapy is seldom recommended for management of otitis media with effusion (Lee et al., 2009). Proper diagnosis of acute otitis media and otitis media with effusion is essential in the primary care setting due to differences in their diagnosis, management, and treatment. The purpose of this paper is to evaluate the literature on current practice guidelines for the diagnosis and treatment of otitis media with

effusion, evaluate prescribing practices of providers, and compare them to current practice guidelines.

### **Statement of the Problem**

Otitis media is a leading cause of childhood healthcare visits worldwide (Qureishi et al., 2014). The World Health Organization has designated otitis media management skills as a priority for primary care providers due to the prevalence of the diagnosis (Lee et al., 2009). Proper diagnosis and management of otitis media, specifically otitis media with effusion compared to acute otitis media, is essential for providers working with the pediatric population. Otitis media diagnosis has a large impact on medical expenditures. There are over 2.2 million episodes of otitis media with effusion diagnosed annually in the United States (Lee et al., 2009). This equates to over \$4 billion in direct annual health care costs (Rosenfeld et al., 2016). Otitis media with effusion is also very common in infants. It is estimated that over 50% of children will experience otitis media with effusion by their first birthday (Rosenfeld et al., 2016). Even with the high incidence of OME, research has shown the majority of these infections resolve spontaneously within the first three months of symptom onset. The cumulative effect of the evidence suggests otitis media plays a significant role on healthcare costs, prescription costs, and the morbidity of children in the United States.

The original practice guideline for managing otitis media with effusion was developed in 1994 by the Agency for Healthcare Research and Quality (Rosenfeld et al., 2004). This guideline was limited and only included children one to three years old without craniofacial or neurologic abnormalities or sensory deficits. The guideline was updated in 2004 by the American Academy of Pediatrics, American Academy of Family Physicians, and American Academy of Otolaryngology-Head and Neck Surgery (Rosenfeld et al., 2004). This guideline expanded to include children two months to 12 years of age with or without developmental



disabilities and underlying conditions. The 2004 guideline made 11 recommendations on the diagnosis, treatment, and management of OME (Rosenfeld et al., 2004). This clinical practice guideline was subsequently updated in 2016 to incorporate additional evidence-based recommendations for the diagnosis, treatment, and management of otitis media with effusion (Rosenfeld et al., 2016). The 2016 updated guideline expanded on the 2004 recommendations, incorporated new research and systematic reviews, and also added new recommendations and algorithms to aid in decision making for management of OME.

Notably, the OME clinical practice guideline recommends against the use of antibiotics for otitis media with effusion and instead recommends watchful waiting for three months from symptom onset (Rosenfeld et al., 2016). This is due to evidence showing that most otitis media with effusions resolve spontaneously within that timeframe. OME often occurs during an upper respiratory infection, due to poor eustachian tube function, or following an AOM (Rosenfeld et al., 2016). Despite the guidelines and research evidence, 32% of providers continue to treat OME with antibiotics (Rosenfeld et al., 2016). This inappropriate use of antibiotics leads to unnecessary adverse reactions from antibiotics, adds to antimicrobial resistance to antibiotics, and increased healthcare costs.

The Centers for Disease Control and Prevention ([CDC], 2015) defines antimicrobial resistance as a mutation of microbes or bacteria to resist the effects of drugs that once were effective in treating an infection. The CDC found up to half of all prescribed antibiotics are considered inappropriate for the intended diagnosis or are prescribed with incorrect dose and/or duration. The World Health Organization ([WHO], 2018) has also expressed concern that antimicrobial resistance is on the rise and threatens the treatment of diseases. This antimicrobial resistance occurs over time but is accelerated by the unnecessary and inappropriate use of antibiotics (WHO, 2018). Due to these concerns, the Joint Commission has enacted an

antimicrobial stewardship standard for hospitals, nursing care centers, ambulatory care centers, and office-based surgery practices. This standard requires leaders to establish an antimicrobial stewardship program as an organizational priority (Joint Commission Perspectives, 2016). The Joint Commission has required organizations to educate staff on antimicrobial stewardship and antibiotic resistance. It is essential that providers practice and understand antibiotic stewardship, but now the Joint Commission has made it a requirement.

A data analysis of antibiotic prescribing for OME diagnoses was performed at a Midwestern pediatric hospital in 2017. This data included the number of patients with OME diagnoses and the rate of antibiotic prescribing within the hospital's three suburban urgent cares. The pediatric hospital's Infectious Disease department found that 54.49 to 83.5% of patients diagnosed with OME were prescribed antibiotic treatment. This hospital collected data that showed overall 811, or 75.7%, of the 1,071 patients diagnosed with otitis media with effusion were prescribed antibiotics. This is in direct contrast to the current practice guideline that do not recommend antibiotics for otitis media with effusion (Rosenfeld et al., 2016). These results call to question provider rationales behind current prescribing practices for otitis media with effusion. As the concern for antibiotic resistance rises, it is essential providers use judicious antimicrobial prescribing practices.

### **Project Aims**

The purpose of this project was to evaluate antibiotic prescribing practices among health care providers. Provider knowledge in the diagnosis, treatment and management of OME was assessed through the use of a descriptive survey. The project also evaluated prescribing practices and correlations or potential influencing factors for current OME prescribing practices at three pediatric suburban urgent care centers.

### **Author's Assumptions**

Providers surveyed all cared for pediatric patients. Therefore, it was assumed all surveyed providers care for patients with complaints of ear pain as well as OME diagnoses. It was also assumed that the increased antibiotic prescription rate at the hospital's urgent care center were due to multiple influencing factors. These factors included, but were not limited to, the need for further education on the diagnosis, treatment, and/or management of OME. Providers may have been experiencing difficulty in distinguishing OME versus AOM and had a misunderstanding of antimicrobial treatment recommendations. Other potential factors included the following: parental pressure for antibiotics during the patient encounter, concern of parental satisfaction scores, risk and liability of mis-diagnosing a patient, and using professional experience that goes against the OME guidelines. Another potential influencing factor was that, as previously mentioned, treatment recommendations were updated in 2016 and not all providers may be up to date on the current guidelines (Rosenfeld et al., 2016). More than one of the previously mentioned factors may be involved in the increased antimicrobial rates for OME. An anonymous survey of providers allowed evaluation of the assumptions to better identify barriers to following the 2016 OME practice guidelines.

### **Literature Review and Synthesis**

The literature search involved multiple search engines and search words to fully encompass the project. The search engines included CINAHL, ClinicalKey, PubMed, Google Scholar, Cochrane Library, and Sanford Guide for Antimicrobial Therapy. The search was limited to articles published in the last 20 years. Studies performed to understand provider prescribing practices were also included in the literature review, however, limited research was found that specifically assessed prescribing practices for otitis media with effusion. Literature

regarding antimicrobial resistance was also included in the review. Only articles in English were included for the review.

### **Inclusion and Exclusion Criteria**

Search words and MESH terms varied in attempt to find an encompassing number of articles that fully represented the research question. Search words were modified throughout the research collection process and included the following: “prescribing practices,” “antibiotic prescribing practices and survey,” “prescribing practices and survey and upper respiratory tract infection,” “prescribing practices and survey,” and “otitis media with effusion and treatment and survey.” Other search words included the following: “epidemiology, natural history, and risk factors;” “panel report from the ninth international research conference on otitis media;” and “epidemiology, natural history, and risk factors for otitis media.” The search terms used were specifically selected to gather information on the epidemiology and risk factors for the diagnosis in question. Additional search terms included the following: “antibiotic resistance,” “antibiotic resistance and otitis media,” “over treatment of ear infections,” and “otitis media with effusion and antibiotics.” The terms “otitis media with effusion versus acute otitis media,” “otitis media and treatment and diagnosis,” “current practice guideline, otitis media, and middle ear effusion,” and “otitis media with effusion treatment” were used to gather literature on evidence-based research for treatment of otitis media with effusion.

The following inclusion criteria were used for the literature search: 1) 2016 or 2004 clinical practice guidelines for OME; and 2) included children from two months to 18 years of age. Studies were also included if they discussed surveying prescribing practices of providers for management of upper respiratory infections or otitis media. Literature regarding antimicrobial resistance, the effects of overprescribing antimicrobials, and antimicrobial resistance in relation to otitis media were also included in the literature synthesis. These

inclusion criteria were developed to enable the most inclusive but still significant data to have a well-rounded literature review.

Exclusion criteria were also utilized in evaluating appropriate literature for the study. Literature was excluded if it 1) did not use current practice guidelines; 2) involved children with high-risk conditions; 3) involved persons over the age of 18 or less than two months of age. The age limit was set in order to comply with the current clinical practice guidelines age range for recommendations (Rosenfeld et al., 2016). Studies were excluded if they did not follow the 2004 or 2016 clinical practice guidelines or if they did not discuss otitis media with effusion. The exclusion criteria used in the literature search were to enable the most accurate and relevant data to be found for the study.

### **Overview of the Literature**

The literature was replete with information for the diagnosis, evaluation, and management of otitis media with effusion (OME). Otitis media with effusion has been characteristically defined and agreed upon as a collection of fluid in the middle ear without acute symptoms such as otalgia, pus, and fever by several organizations including the CDC, AAFP, AAP, AAO-HNS (CDC, 2017; Harnes et al., 2013; Rosenfeld et al., 2016). The CDC alone noted viral symptoms such as rhinitis, cough, and diarrhea are often present in patients with OME. Otitis media with effusion often follows AOM infections but symptoms of otalgia, fever, and malaise usually resolve (Robb & Williamson, 2016). It is thought the fluid in the middle ear could vary from serous to thick or mucoid while causing temporary and reversible hearing loss (Robb & Williamson, 2016).

The 2016 clinical practice guideline for managing otitis media with effusion was co-developed by the AAO-HNS, the AAP, and the AAFP and used as the basis of this literature review (Rosenfeld et al., 2016). The 2016 guideline was an update from the 2004 guideline with

expansion of evidence including four new clinical practice guidelines, 49 additional randomized controlled trials, and 20 new systematic reviews, all expanding on previous recommendations. The 2004 clinical practice guideline was developed based on the literature of 970 studies including randomized controlled trials, prospective cohort studies, and validating cohort studies (Rosenfeld et al., 2004). The 2016 guideline included 13 statements and recommendations, but this project focused specifically on statement 8b that recommended against the use of antibiotics for the treatment of otitis media with effusion (Rosenfeld et al., 2016). Other recommendations for OME included use of pneumatic otoscopy, and for patients not at high risk, there was encouragement for three months of watchful waiting and discouragement of antihistamines or decongestants (Rosenfeld et al., 2016). It was evidenced in the 2016 guideline that antimicrobials did not affect long-term outcomes in OME, but that decreasing the use of these medications would significantly impact healthcare costs and potential for adverse events. Avoiding antimicrobials in the treatment of OME will decrease rates of inappropriate prescribing and improve bacterial resistance (Rosenfeld et al., 2016). Overall the clinical practice guideline provided a comprehensive evaluation of current research which offered providers a foundation for standards in practice.

In a prospective cohort study to assess family physician knowledge in the diagnosis of otitis media, a total of 25 family physicians responded to a developed survey that evaluated knowledge of risk factors, signs and symptoms, use of pneumatic otoscopy, and treatment regimen for otitis media (Lee, Flowerdrew, & Delaney, 2009). The survey used was deemed to have excellent internal consistency and test-retest reliability. This study was an example of how use of a well-developed survey can be a powerful tool in understanding provider knowledge.

Studies involving antibiotic use in the treatment of OME were evaluated in the literature with findings similar to that of the 2016 OME clinical practice guidelines, which recommend

against the use of antimicrobial therapy in the treatment of OME (Rosenfeld et al., 2016). In a systematic review which included 23 randomized controlled trials, sampling 3,258 children, the benefits and harms of oral antibiotics were assessed in children diagnosed with OME (Venekamp et al., 2016). Findings within these trials produced insufficient evidence to validate the use of antibiotics in the treatment of OME. It was also found antibiotic therapy did not decrease tympanostomy tube placement in children and was more likely responsible for adverse reactions such as diarrhea, vomiting, and rash (Venekamp et al., 2016).

Although this project evaluated OME treatment, it is also important to recognize that judicious use of antimicrobial prescribing has been recommended even in the treatment of AOM. The AOM clinical practice guideline recommended watchful waiting over antimicrobial therapy based on certain case scenarios including the presence of fever, severity of otalgia and diagnostic findings, and laterality of symptoms (AAP, 2013). The importance of prudent antibiotic use was evidenced in a systematic review that assessed the effectiveness of antibiotics for AOM compared to a placebo in thirteen randomized controlled trials (Venekamp et al., 2015). Immediate antimicrobial treatment was compared to observation and found 60% had symptom improvement within 24 hours from start of treatment whether the participant received the antibiotic or placebo. No statistical significance in reduced pain scores were found between either group within the first 24 hours of treatment (Venekamp et al., 2015). Overall antibiotics had a slight improvement in symptoms, but watchful waiting continued to be recommended for the majority of patients.

Even though evidence indicates antibiotics are ineffective in the treatment of OME and may increase adverse reactions, providers continue to prescribe antimicrobials. As an example, a cross-sectional survey evaluated provider use and understanding of the current OME practice

guidelines (Harvey, Bowe, & Laury, 2016). Researchers found only half of the surveyed participants used a clinical practice guideline in the management of OME.

Similar results were found by a study that looked at rates of patients diagnosed with OME who received an antibiotic prescription (Roditi, Liu, Bellmunt, Rosenfeld, & Shin, 2016). This study also assessed if rates varied according to clinical practice setting. This was a large study that comprised of 1,390,404,196 patient visits. Results found 32% of patients diagnosed with OME were prescribed antibiotic treatment. The highest rates of antibiotic prescribing were found to be in the emergency departments when compared to the primary care settings (Roditi et al., 2016). These results were comparable to another study that found there to be an 18.8% increased risk for antibiotic prescribing in patients diagnosed with OME (Roditi, Rosenfeld, & Shin, 2017). These results show significant and continuous use of antibiotic treatment for the management of otitis media with effusion even after the 2004 and 2016 clinical practice guidelines recommended against use of antibiotics (Roditi et al., 2016). Findings from these studies indicate a need for quality improvement projects aimed at evaluating barriers to following current practice guidelines (Roditi et al., 2017).

Although providers continue to prescribe antibiotics for OME, there is research that indicates providers are aware and concerned about the effects of overusing antimicrobials. This was identified through a survey assessing physician perceptions of antimicrobial resistance and perceived barriers to judicious use of antibiotics (Wilcok, Wisner, & Powell, 2016). A total of 40 physicians completed the survey. All of the surveyed physicians were concerned for continued resistance and felt antimicrobial resistance was a true threat to patient welfare (Wilcok et al., 2016). The authors found just over half of the surveyed participants felt pressured by patients for antibiotic prescriptions. Results of this survey highlighted provider awareness and



concern about antimicrobial resistance, but that patient pressure may also be a cause for overprescribing of antibiotics (Wilcok et al., 2016).

Antimicrobial resistance may be the rise, but appropriate prescribing practices could slow the rate of resistance (Colgan & Powers, 2001). Resistant bacteria develop in a community when the same antibiotic is prescribed to a large number of people in the community. Colgan and Powers (2001) discussed a study out of Finland that found resistance rates of erythromycin declined from 16.5% to 8.6% over a four-year period during a nationwide initiative to reduce prescribing rates of erythromycin (Seppala et al., 1997). Studies in the United States have also found a correlation between the decreased use of antibiotics for prophylactic treatment and rates of resistant organisms (Colgan & Powers, 2001). Patient perception of antibiotics also has an effect on prescribing practices. Patients have become accustomed to receiving an antibiotic for diagnoses that are known to be viral in nature or that usually resolve without antimicrobial treatment. This then causes difficulty for patients to understand why they are not being treated with an antibiotic when they have previously received antibiotics for similar symptoms (Colgan & Powers, 2001). It is imperative providers educate and discuss the potential complications of antibiotics with patients and families to aide in the understanding of antibiotic stewardship.

### **Theoretical Framework**

Donabedian's Quality Framework served as the conceptual framework for this project. This framework uses the structure-process-outcome model as a tool for accelerating quality improvement projects in the healthcare setting (McDonald et al., 2007). The goal of this theoretical framework was to efficiently and concisely develop a plan for implementing and evaluating a change in current practice through the use of three related concepts. The first step in the model was to determine the structure or physical and organizational aspects of the health care setting. For this project the setting included three free standing suburban urgent care sites and

the providers that work in each of the three areas. The core of the model was the process (McDonald et al., 2007). This included the course of patient care and the plan of care development. This process portion of the model was be the main focus of the project. The process was assessed to understand provider prescribing practices for patients diagnosed with OME. Results from the assessment were then analyzed to determine the final step in the process: the outcome. This portion of the model aimed to improve patient health and overall patient outcomes (McDonald et al., 2007). The outcome portion assessed barriers to the use of current practice guidelines for OME and aimed to improve overall antibiotic stewardship.

### **Methods**

The project design used an evidence-generating method to gather information on current prescribing practices for OME at a large Midwestern tertiary care children's hospital. This hospital was chosen for the project due to their current antibiotic stewardship initiatives and recent data collection that showed a high rate of antibiotic prescribing for OME in their urgent care sites and emergency departments. This project focused on the three free standing pediatric urgent care sites affiliated with the hospital.

#### **Project Design**

Permission from the hospital's Urgent Care Division Director was obtained before the project was initiated (see appendix A). Approval for implementation of the project was also received by the Midwestern hospital's Institutional Review Board (IRB) (see appendix B). Additionally, IRB approval at the University of Kansas Medical Center was received prior to commencement of the project (see appendix C).

The project followed a descriptive survey design. The survey invitation was electronically sent to each of the providers, both physicians and advanced practice registered nurses (APRNs), who care for patients at any one of the designated locations. The total sample

included providers who work primarily in the urgent cares as well as providers who pick up extra shifts, or moonlight, at the urgent care sites. This allowed for a broader sample population to increase reliability of the survey results.

### **Data Collection Instrument**

Survey questions ascertained: knowledge of the OME diagnosis and treatment, knowledge and use of current practice guidelines, and factors associated with adherence to the guidelines. Both subtypes of otitis media were discussed in the survey with the main intention to understand prescribing practices for OME. Inclusion of both diagnoses allowed the principle investigator to discern a potential knowledge gap of diagnostic criteria for AOM versus OME. Survey questions were directed toward provider practices and did not involve patient information. These questions aimed to understand prescribing practices, direct future antibiotic stewardship initiatives, and identify barriers to following the OME practice guidelines. No protected patient health information or identifiable survey participant information was collected for this project. The survey was piloted by five APRNs who were given the opportunity to make modification recommendations. These included one APRN from an outpatient primary care setting and four APRNs from the Midwestern hospital's emergency departments. See appendix D for an example of the survey.

### **Data Collection Methods**

The survey instrument was developed using Research Electronic Data Capture (REDCap) through The University of Kansas. This system is a secure, web-based electronic data tool used for research and quality improvement (REDCap, n.d.). Through the use of this tool the investigator was able to send, collect, and track all submitted surveys. The survey was open for a period of four weeks with a weekly reminder email sent to all providers. This reminder email was sent to all potential participants, regardless if they had previously completed the survey.

Providers were able to exit the survey without having completed all questions, but were not able to return to their partially completed survey. Some questions were required prior to submitting the survey to ensure all demographic data was collected. All open-ended questions remained optional and were not required in order to submit the survey. If the survey was incomplete, the provider had the option to submit it without answering all questions or to start the survey over at a later time. Each of the hospital's urgent care providers and providers who pick-up extra shifts at one of the urgent care sites received an invitation email with a link to complete the survey. This invitation link was sent through the hospital's server. A description of the survey was provided in the email along with education regarding the overall goal of the survey (see Appendix E). Potential participants were instructed that survey completion was optional and answers would remain anonymous. This was done to ensure participants understood the reasoning for the survey and unidentified design nature of the results in attempt to reduce potential response bias.

### **Data Analysis**

Descriptive statistics were used to describe the sample and percentages were calculated to report the survey results. Data was exported to a Microsoft Excel document for analysis. Statistical analyses were divided by question and healthcare provider role to track potential trends. Tables, bar graphs, and pie graphs were created to display the findings. The responses to open-ended questions were analyzed and compiled into categories.

### **Results**

One hundred and nine providers were given the opportunity to complete the survey. From this total, 48 providers worked primarily in one of the three urgent care sites and included 14 APRNs and 34 physicians. The remaining 61 providers were considered moonlighter physicians for the urgent care. A total of 47 surveys were completed for an overall 43%

response rate. There were eight partially completed and 39 fully completed surveys. Of note, 39 of the total 47 survey responses were completed by core providers and indicates an 81% response rate from the core urgent care providers. Twenty-nine core urgent care physicians (61.7%), 10 core APRNs (21.3%) and eight (17%) moonlighter physicians responded to the survey. See appendix F for further breakdown of healthcare provider role type. APRN responses were divided between pediatric and family nurse practitioners. This was done to determine if there was a significant difference between responses by a pediatric versus family nurse practitioner. There were seven family nurse practitioners and three pediatric nurse practitioners that responded to the survey and no significant difference was found between the two nurse practitioner role types.

Providers were first asked to indicate their years in practice. This was to determine if the number of years in practice was associated or had a relationship with responses regarding the diagnosis and management of OME or the barriers to following the OME guidelines. Approximately 47% of the providers had 11 or more years of practice and of these responses, three were APRNs and 19 were physicians. See appendix G for further breakdown of provider years in practice. Providers were also asked to indicate which urgent care they primarily practiced or if they were a “float” to the three urgent care sites. This assessed for a relationship between responses and the urgent care in which they primarily practice. No significance was found between antibiotic prescribing or diagnosis and treatment options and the provider’s primary urgent care location.

### **Diagnosis and Treatment**

Participants were given a scenario question that asked the provider to select the best treatment option (see appendix H). This question gave an example of a three-year-old child with a low-grade fever and a gray, opaque, non-bulging or retracted tympanic membrane. Providers

were asked to choose the best treatment from the following, “no antibiotic,” “antimicrobial therapy,” “antihistamines and/or decongestants,” and “intranasal steroids.” Approximately 78% of the providers correctly indicated “no antibiotic” as the best treatment option. There were six participants who recommended antihistamines and/or decongestants for treatment, two providers indicated antimicrobial treatment, and two providers that recommended intranasal steroids for patient management. These results indicate an overall strong provider knowledge of the treatment for OME.

Survey participants were also asked an OME diagnosis question and to “select all that apply” for the signs and symptoms of OME. The majority (89%) of the responders correctly identified a middle ear effusion as a sign of OME. However, the responses showed a knowledge deficit for other signs and symptoms of OME. Mild erythema was indicated as a symptom of OME by only 33% and moderate erythema for OME by 18% of participants. Approximately 35% of participants correctly indicated lack of bulging tympanic membrane as a symptom of OME, and 24% indicated a bulging tympanic membrane as a sign of OME. Regarding temperature symptomology, close to half of the providers correctly indicated a “low-grade or no fever” as a symptom of OME. There were 15 participants (32%) who indicated symptoms of OME could include both a lack of bulging tympanic membrane and middle ear effusion. Of these 15 participants, only eight correctly indicated the patient could have mild erythema to the tympanic membrane. See appendix I for further information. These results indicate provider education on the various signs and symptoms of OME would be beneficial to practice in the urgent cares.

Participants were then presented three images of tympanic membranes and asked to identify if the photo was of an acute otitis media or otitis media with effusion. The majority of the surveyed providers correctly identified the three pictures of tympanic membranes. Two of

the three pictures provided were incorrectly identified by merely two different participants. Only one provider incorrectly identified all three photos. These results support the participants have a strong understanding of the visualization of an OME versus AOM.

### **Influencing Factors**

Providers were asked to rank a set of potential influencing factors on how likely each factor was to influence their decision for diagnosing and treating OME outside the practice guidelines. The rankings included the following options: “no likelihood,” “low likelihood,” “somewhat likely,” and “very likely.” The influencing factors that were evaluated included the following: parental pressure during the patient encounter, professional experience, risk and liability of mis-diagnosis, and parental satisfaction scores. Providers were also given the option to free-text “other” influencing factors.

Overall the most influencing factor was professional experience with 41% of providers who indicated this was “very likely” to influence their decision. All except for one of these “very likely” responses were indicated by physicians. The vast majority of nurse practitioners that responded in the survey indicated professional experience had “no likelihood,” “low likelihood,” or was “somewhat likely” to influence their diagnosis and treatment for OME. The potential for risk and liability of mis-diagnosis was the second most common influencing factor, with 27% of the surveyed providers indicating it was “somewhat likely” to influence decision making. This selection was indicated by both physicians and nurse practitioners.

Parental satisfaction scores were found to be a “somewhat likely” influencing factor in 18% and low likelihood in 46% of surveyed providers. See appendix J for further breakdown of responses. Although providers indicated there was a low risk of parent satisfaction scores influencing their decision, 64% indicated at least a slight chance of this being a contributing factor. Out of the total ten nurse practitioners that responded to the survey, half indicated

parental satisfaction scores had a low likelihood of influencing their decision making and the other half indicated there was no likelihood for influence.

Another similar influencing factor was parental pressure during the patient encounter. A total of 68% of providers felt parental pressure was either a “low likelihood” or “somewhat likely” to influence their decision making for treating OME. Although 23 out of the 30 who answered this question felt it was a “low likelihood” to influence their decision, it was still a consideration. There were nine out of ten nurse practitioners who indicated parental pressure had a low likelihood to influence their decision and one indicated there was no likelihood. See appendix J for further detail on rates of influencing factors.

Text data were also gathered through open-ended questions. Providers were asked to indicate any “other” potential influencing factors in their decision to go against the OME practice guidelines for the treatment of OME. There were five providers who indicated “other” influencing decision making factors. These factors comprised the following: patient history and timing of presentation, ear pain level, age of the patient, if the patient had a fever during the encounter, if the OME was bilateral, and insufflation of the tympanic membrane. One provider also indicated it would influence his/her decision making if the family could follow watchful waiting instructions or if the child would be traveling and leaving the area soon.

### **Clinical Practice Guideline Usage**

Providers were asked if they had reviewed the 2016 OME guidelines. The majority of the surveyed providers (74%) indicated that “yes,” they have reviewed the guidelines and also use them to treat OME. Most of the providers also provide family education consistent with these guidelines. When education was not provided, it was either due to lack of time or because the provider was not familiar with the guidelines.



## **Cerner Diagnoses**

The final three questions each displayed a picture of a tympanic membrane and asked the provider to free-text the diagnosis or diagnoses they would use for the provided image. These images were the same as the ones used earlier in the survey that asked if it was a picture of an AOM or OME. See Appendix D for the survey. The first picture was of an AOM. In the earlier question, all but two providers correctly identified this same photo as AOM. When asked what diagnosis the provider would provide for the same picture, two providers used “otitis media with effusion” as the diagnosis. There were 24 providers who used “acute otitis media” as the diagnosis, seven who used “acute suppurative otitis media,” five who used “otitis media,” one used “suppurative otitis media,” and one that indicated “purulent otitis media.”

The second picture was of a tympanic membrane with an OME. A total of 27 providers indicated they would use the diagnosis of “otitis media with effusion” for the photo and seven gave the diagnosis of “serous effusion.” There were two providers that gave the diagnosis of “effusion,” and one provider for the following diagnoses: “fluid in middle ear,” “middle ear effusion and eustachian tube dysfunction,” “ear pain,” and “acute otitis media.”

The third picture was an AOM presentation. There were 22 providers that gave the diagnosis of “acute otitis media,” nine diagnosed as “acute suppurative otitis media,” and two providers diagnosed the photo simply as “otitis media.” The following diagnoses were indicated by one participant each: “acute otitis media with effusion,” “purulent otitis media,” “otitis media with effusion,” and “purulent effusion.”

## **Discussion**

The primary goal of this project was to evaluate provider prescribing practices for otitis media with effusion in the pediatric urgent care setting. The survey findings indicated that for the majority of pediatric providers, there was a good understanding for the diagnosis and

treatment of otitis media with effusion, but that further education would be beneficial. In the clinical scenario question for treatment of OME, approximately 22% of the providers recommended treatment with antihistamines and/or decongestants, intranasal steroids, or antimicrobials. Of note, these results did not coincide with the previous 2017 survey that concluded a 75% rate of antibiotic prescribing for OME. Another potential need for increased education was identified when providers were queried for the diagnosis, and asked to select all potential signs and symptoms of OME. The clinical practice guidelines do not recommend the use of antimicrobials, antihistamines and/or decongestants, or intranasal steroids for the treatment of OME (Rosenfeld et al., 2016). Insufficient evidence has been found to indicate these other treatments improve the duration or severity of OME. Responses to this question revealed the majority of providers agreed with the clinical guidelines but further education on the evidence-based guidelines could be beneficial.

It was also found that providers had mixed results when asked to select all signs and symptoms that would be used to document an OME. The overwhelming majority of the providers considered a middle ear effusion to be required for an OME diagnosis. However, less than half of the providers correctly identified “lack of bulging tympanic membrane” or “mild erythema” as possible signs of OME. Additionally, only about half of the providers indicated a “low-grade or no fever” would be a symptom of OME. Otitis media with effusion is defined as a normal positioned or retracted eardrum with reduced mobility, transient fluid in the middle ear, but without signs of acute inflammation or infection (Lee et al., 2009) (Rosenfeld et al., 2016) (Harmes et al., 2013). With this definition in mind, although the option “lack of bulging tympanic membrane” is correct, it may have potentially caused confusion among providers. Responses to this question indicated further education of the inclusion diagnostic criteria for an OME would be beneficial for the providers in the urgent care sites.

Parental pressure, satisfaction scores, and risk of liability and mis-diagnosis were found to be only slight considerations for many providers when making treatment decisions for patients with OME. There was however an increased potential for providers to choose their professional experience over the guidelines when felt it would be warranted. Approximately 40% of the surveyed providers indicated professional experience was “very likely” to influence the decision for diagnosing and treating OME outside the clinical practice guidelines and of those, 61% had seven or more years of experience as a healthcare provider. Due to these results, discussion on the significant amount of evidence that supports the guideline recommendations could be considered when developing the next steps in this process.

Lastly, providers were asked to indicate what diagnosis or diagnoses he/she would chart when provided the same three pictures of tympanic membranes. Due to a variety of available classifications for OME and AOM, inconsistency was found among providers when making the final diagnosis. Approximately 30% of responses were classifications other than “otitis media with effusion” and 11% were classifications other than “acute otitis media” or “acute suppurative otitis media.” These other diagnoses were either vague or incorrect to describe an OME or AOM. An example provided was the vague description “ear pain” for the diagnosis for an OME and another was “eustachian tube dysfunction.” Examples of incorrect provider responses for AOM were “otitis media” and “otitis media with effusion.” These mixed diagnoses elucidate the need to simplify the diagnoses used for both AOM and OME at the urgent care sites. A recommended next step would be to standardize diagnosis codes for OME and AOM in the urgent care.

### **Limitations**

There were multiple limitations to this project including use of a single hospital, time of year, low response rate of moonlight physicians, anonymity of participants, lack of uniformity in

billing and coding, along with inability to save and re-start the survey. Most significantly, the survey evaluated urgent care sites of only one pediatric hospital. The survey was completed by providers with a healthcare background in pediatrics and involved urgent care sites that were connected to a larger pediatric hospital. Due to this, further studies would be needed to evaluate the generalizability of these results for pediatric urgent care sites across the region. Another limitation was the time of year the survey was conducted. This season is generally a heightened time for pediatric illness and even though reminder emails were sent, this may have influenced provider availability for survey completion. Only eight of 61 moonlighters responded to the survey for a 13% response rate. Even though the total response rate was 43%, the project was not an accurate depiction of the entire department including the moonlight physicians.

Although anonymous, some providers may not have felt comfortable answering the survey questions. A description of the survey was sent in an email along with the survey link. In the email it was explained the survey would remain completely anonymous. Even with this in mind, providers may have felt uncomfortable completing the survey due to concern for potential backlash based on survey results that may influence billing. Providers may not have answered questions completely independently and honestly due to the same concern. This may be a reason the survey results did not align with the original data collected in 2017 relative to antibiotic prescribing rates for OME.

Another limitation was billing and coding, which was not evaluated alongside the survey. Providers in the urgent care at this facility are required to provide a diagnosis or diagnoses codes for a patient encounter, but do not provide the billing and coding of the encounter. Providers were asked to indicate the diagnosis or diagnoses when offered pictures of AOM and OME. It was hoped to evaluate potential need for alignment of nomenclature or classification in billing and coding of these diagnoses. This project was the first step in assessing this potential concern,

but did not evaluate how the billing and coding department arrive at their decisions based on the provider diagnoses. Since the results of the survey do not coincide with the previous data analysis, it would be important to consider this as a next step to rule out potential issues with this department.

Finally, the inability for providers to save or resume their surveys was identified as another potential limitation. Despite attempts to make the survey easier to complete, it was not possible to allow providers to save and re-start a partially completed survey. This aspect may have been a hindrance during the heightened season of illness and provider time constraints. Not allowing the provider to save a partially completed survey could have impacted the total number of completed surveys.

### **Dissemination of Results**

Results of this descriptive survey were disseminated in several ways. First, the survey results and data analysis were discussed with the project chair and co-chairs through the University of Kansas School of Nursing. The results of the survey along with the data analysis were then disseminated through a meeting with the Urgent Care Division Director, Infectious Disease physician that aided with the project, and the mentor for the project at the Midwestern pediatric hospital. Recommendations for the next steps and educational opportunities gained from this project were discussed during this meeting. Finally, the results and data analysis were communicated to the University of Kansas School of Nursing through a public presentation.

### **Recommendations for Future Research**

This descriptive survey project was the first step in the overall aim to improve antimicrobial stewardship for otitis media with effusion in the urgent cares. The project aimed to evaluate prescribing practices of providers who diagnose patients with otitis media with effusion. Results of the survey show a need for further education on the signs and symptoms of OME and

education on the evidence-based OME practice guideline recommendations. Future research may consider re-sending the same survey to only the moonlighting providers in attempt to gather more data. The next steps would include an educational program of the providers to discuss OME signs and symptoms, update providers on the practice guidelines and encourage use of these in practice, develop standardized diagnosis codes for both OME and AOM, and an initiative to educate parents on the importance of antimicrobial stewardship for children diagnosed with OME. Since the survey results did not coincide with the previous antimicrobial rates found in the 2017 analysis, next steps should also include an evaluation of the billing and coding for the diagnoses given by the providers in the survey.

### **Conclusion**

Otitis media with effusion is one of the most common causes of pediatric visits in primary care and a significant cause for antibiotic prescriptions in the pediatric population (Marom et al., 2014). The OME clinical practice guidelines were updated in 2016 and recommended against the use of antimicrobial treatment for OME (Rosenfeld et al., 2016). Providers continue to prescribe antibiotics for OME diagnoses which can lead to increased rates of adverse events and overall increased antimicrobial resistance (Roditi et al., 2016) (Roditi et al., 2017) (Rosenfeld et al., 2016). Results of a data analysis performed at the Midwestern pediatric hospital found 75.7% of patients diagnosed with OME in their associated urgent care sites were prescribed antibiotic treatment. Due to these results, a descriptive survey was compiled and sent to all providers in the urgent cares. This survey aimed to evaluate prescribing practices of the providers and identify future educational needs for the diagnosis, treatment, and management of OME as well as recommendations to decrease barriers for following the clinical practice guidelines. Overall results of the survey indicated a need for further investigation of the billing and coding for these diagnoses and exploration of implications for lower parent

satisfaction scores. Results of the survey also indicated a need for education on the clinical practice guidelines and review of the evidence to support these guidelines, education of the signs and symptoms of OME, and increased parent education of antibiotic stewardship. This project was the first step in reducing overuse of antibiotics in the pediatric urgent care setting with the aim to ultimately improve overall antimicrobial resistance.

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**Appendix A**  
**Collegial Letter of Support**



2401 Gillham Road  
Kansas City, Missouri 64108  
(816) 234-3000

June 21, 2018

To Whom It May Concern:

This is a letter of support for Brianna Kuster in her project, "A Pilot Project to Understand Prescribing Practices of Otitis Media with Effusion" at the three Children's Mercy urgent cares. This will be an anonymous survey of the providers that care for patients in these three departments. Information gathered from this survey will aid in future quality improvement projects on antibiotic stewardship and reducing antibiotic prescribing for otitis media with effusion in the urgent cares.

Sincerely,

Jennifer Johnson, MD, FAAP  
Director, Division of Urgent Care  
Children's Mercy Kansas City

## Appendix B

### Hospital IRB Form



### HRP-221 – FORM - NOT HUMAN SUBJECTS RESEARCH DETERMINATION (QUALITY IMPROVEMENT PROJECT)

This form is to be used to submit Quality Improvement project plans to the Office of Research Integrity (ORI) for determination as to whether or not the project involves human subjects research needing IRB review.

**Quality Improvement** is the combined efforts of everyone to make the changes that will lead to better patient outcomes (health), better system performance (care), and better professional development (learning).<sup>1</sup>

Sometimes, QI projects also involve **human subjects research**.

#### INSTRUCTIONS:

To submit your QI project plan for a **Not Human Subjects Research Determination**:

1. Go to **myIRB** (<http://myresearch/irb>) and select "Create New Study."
2. On the *Basic Information* page of the SmartForm, where it asks you to attach a protocol, attach this completed **HRP-221 – FORM**.
3. Hit "Continue" to advance through the SmartForm and answer the remaining questions. Be sure to upload your "Measures" on the "Local Site Documents" page under "Other Attachments." (See details on page 4 of this form.)
4. Once you hit "Finish" at the end of the form, select "Submit" to submit your project for review.

Once submitted, ORI staff will evaluate whether your project qualifies for a determination of *Not Human Subjects Research*. If it is determined that your project does indeed involve human subjects research you will be instructed on how to submit for IRB review.

Your QI project plan will also be shared with the *Quality & Performance Improvement Center for Clinical Effectiveness* for additional review and support of your project.

If you have any questions please contact ORI at (816) 701-4358 (x44358) or [irb@cmh.edu](mailto:irb@cmh.edu).

<sup>1</sup>[Batalden, PB: "What is 'quality improvement' and how can we transform healthcare?," *Qual Saf Health Care*, 20007 16(1): 2-3.]



### Research Determination Questions

1. Is the goal of this project to produce knowledge that will *immediately* improve...
  - a. A process or program; OR
  - b. A Children's Mercy system; OR
  - c. Patient outcomes?

☒ Yes  
☐ No
  
2. Does the project involve care practices, interventions, or treatments that are NOT standard (neither consensus-based, nor evidence-based)?
 

☐ Yes  
☒ No
  
3. Is one of the goals of this project to *develop* a national standard of care or a national benchmark to be applied outside of Children's Mercy?
 

☐ Yes  
☒ No
  
4. Does your project involve randomizing individuals from similar populations into two or more comparative groups? For example, are patients/providers randomized into different intervention groups in order to enhance confidences in differences that might be obscured by non-random selection?
 

☐ Yes  
☒ No
  
5. Will this project...
  - a. Involve the use of human specimens to test an in-vitro diagnostic device; OR
  - b. Be done to support an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application being submitted to the FDA; OR
  - c. Include collection of data to be held for inspection by the FDA or submitted to the FDA for any purpose?

☐ Yes  
☒ No



## QI Project – Background Information

1. Describe the aim of this QI project. In your response be sure to identify:
  - a. The patient population; AND
  - b. Measurable, time-specific objectives of the project (SMART Aim: Specific, Measurable, Actionable/Attainable, Realistic, and Time-bound).

For example, "Improve the use of ampicillin as the first line therapy for simple inpatient community acquired pneumonia from 60% to 90% by January 2013."

The purpose of this project is to understand prescribing practices among health care providers in the diagnosis, treatment and management of otitis media with effusion through the use of a descriptive survey. This survey will be sent to Children's Mercy urgent care providers and will be available for a one month timeframe. The survey results will direct provider education and future research on otitis media with effusion and antibiotic stewardship. The overall aim will be to use the knowledge gained from the survey to develop and focus education to reduce inappropriate and overuse of antimicrobials for otitis media with effusion at Children's Mercy Urgent Cares.

2. Start date (or estimated start date) of this project: 10/1/18
3. End date (or estimated end date) of this project: 12/31/18
4. Clarify the problem. State the system, program or process you aim to improve and how you are aware this is in need of improvement.

A clinical practice guideline for managing otitis media with effusion was developed in 2004 and updated in 2016 (Rosenfeld et al., 2016). This guideline incorporates evidence-based recommendations for the diagnosis, treatment, and management of otitis media with effusion. The clinical practice guideline recommends against use of antibiotics for this diagnosis but approximately 32% of providers continue to treat OME with antibiotics (Rosenfeld et al., 2016). This misuse of antibiotics leads to unnecessary adverse reactions from antibiotics, antimicrobial resistance to antibiotics, and increased healthcare costs.

5. Describe the project's intervention(s) or changes for improvement. Why were they selected? If the interventions have not been chosen yet, describe the process by which the intervention will be systematically identified and prioritized.



A convenience sample of APRNs and physicians from the three Children's Mercy urgent cares will be surveyed regarding their knowledge of the guidelines and factors associated with adherence to the practice guidelines. The survey will be sent electronically using REDCap. Questions will ascertain current knowledge of OME diagnosis and treatment, current practice guidelines, and factors associated with adherence to the guidelines. Survey questions will also assess potential influences to prescribing practices. Survey questions will not involve patient information. These questions will aim to understand the prescribing practices, direct education initiatives, and identify barriers to following the OME practice guidelines.

The survey will be available for four weeks with a reminder email to complete the survey sent at the beginning of each week. This specific project design will aide in understanding current prescribing practices of providers and lay the groundwork for future quality improvement projects.



## QI Project - Measures

1. **Add your measure(s):** Adding your measure(s) to your project is a two part process:
  - a. Describe each measure in the table below.
  - b. Then, upload the actual document in your myIRB SmartForm in **Local Site Documents > Other Attachments**.

Name	Type of Measure	Data Source	What is being measured?
Provider Knowledge	Balancing Measure	Survey	Provider knowledge of the definition of otitis media with effusion
Plan of Care	Process Measure 	Survey	Provider diagnosis, treatment, and management of otitis media with effusion
Barriers to care	Process Measure 	Survey	Barriers to following practice guidelines for otitis media with effusion
	Balancing Measure		
	Balancing Measure		
	Balancing Measure		
	Balancing Measure		

2. **How will you graphically display, analyze and share your results?** If your project is not using or run charts or control charts, explain why you are using an alternate format.  
 Results of the survey will be evaluated using the Children's Mercy secure network. Statistical analysis will be divided by question and urgent care center to track potential trends from each specific urgent care. After statistical analysis the results will be reviewed and presented through a document as well as through the use of bar graphs. The bar graphs will show results of each question of the survey compared to each of the three urgent cares. This will allow readers to evaluate variations in answers for providers at each urgent care and compare them to the total sample. These results will be discussed with the Infectious Disease Department to disseminated findings of the survey. Project results will also be shared with the Urgent Care Division Director. Results of the project will be used by the Infectious Disease Department to direct provider education as well as future research on otitis media with effusion and antibiotic stewardship.
3. If available, **attach aggregate baseline data** that has already been collected using any of the measures listed above in your myIRB SmartForm in **Local Site Documents > Other Attachments**.



### QI Project - Management & Oversight

1. Identify the project champion/senior leader for the section/unit/department who has signed off on this project:

Dr. Jennifer Johnson

2. Identify the hospital personnel resources supporting this project (check all that apply):

- ☐ QI Department Consultant (QIC)
- ☐ QI, IS or Informatics Department Data/Decision Support
- ☐ Other Hospital Support

If "Other Hospital Support," specify:

3. Identify the internal department personnel resources supporting this project (check all that apply):

- ☐ Internal Department QI Manager/Expert
- ☐ Internal Department Data/Decision Support
- ☐ Other Internal Department Support

If "Other Internal Department Support," specify:





### QI Project – HIPAA & Data Security

1. Does the data used or accessed for this project relate to:
  - a. The past, present or future physical or mental health or condition of an individual;
  - b. The provision of health care to an individual; OR
  - c. The payment for the provision of health care?

☐ Yes

☒ No

**If YES, then HIPAA regulations apply to this project and you'll need to address questions 2-6 below.**

**If NO, you may skip the remaining questions in this form.**

2. Indicate below which identifiable data elements will be *accessed only* versus which data elements will be *recorded* for the purposes of this project.

Name/Initials	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
All elements of date (except year) directly related to an individual (e.g., date of birth, admission date, discharge date, date of death)	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Medical record number	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Account number	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Health plan identification number	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Social Security Number	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Device identifiers and serial number	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Certificate/License number	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Telephone number	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Fax number	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Email addresses	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Web addresses (URLs); Internet IP addresses	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Street address, city, county, precinct, zip code or equivalent geographical codes	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Full face photographic images and any comparable images	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Biometric identifiers, including finger and voice print	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Vehicle identifiers and serial numbers, including license plate number	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Any other unique identifying number, characteristic or code that may help identify individual participants including their initials (e.g., student or employee ID number)	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded
Elements of date, including year, for persons 90 years or older	<input type="checkbox"/> Accessed only	<input type="checkbox"/> Recorded



3. Identify all anticipated devices where data are expected to reside (check all that apply).

- ☐ Flash drive or other removable media
- ☐ Desktop computer
- ☐ Laptop computer
- ☐ Tablet device
- ☐ Smartphone
- ☐ Internal server (e.g., Dept/Div shared drive)
- ☐ External server

If "External server" is checked, specify where the server is located and who is in charge of maintaining the data:

4. Indicate your plan to protect the confidentiality of electronic records (check all that apply).

- ☐ Password-protected computer
- ☐ Password-protected data files
- ☐ Encrypted data files
- ☐ Database limited to coded data
- ☐ Master list stored in separate location
- ☐ Other

If "Other," please explain:

5. If transferring data outside of Children's Mercy, what method(s) will you be using to transfer the data?

- ☐ Flash drive or portable hard drive
- ☐ CD ROM/DVD
- ☐ Email
- ☐ Secure FTP
- ☐ Website
- ☐ Other

If "Other," please explain:

## Appendix C

## KU Single IRB Form



## REQUEST FOR SINGLE IRB REVIEW

### FOR STUDIES WITH REGIONAL CTSA PARTNERS

(KUMC, CMH, UMKC/TRUMAN, KCUMB, ST. LUKE'S)

**I. STUDY INFORMATION**

Overall Principal Investigator: Brianna Kuster Overall PI's Home Institution: KU School of Nursing

Email: briannakuster@kumc.edu Phone: 913.748.9837 Mail Stop:   
 Alternate Contact Person (e.g., Project Coordinator): Dr. Karen Trees  
 Email: ktrees@kumc.edu Phone: 913.588.1635 Mail Stop:

Protocol Title:

A Pilot Project to Understand Provider Prescribing Practices for Otitis Media with Effusion

**DIRECTIONS:**

1. DOWNLOAD, COMPLETE AND SAVE THIS FORM TO YOUR DESKTOP / FILES.
2. ACCESS THE eIRB SYSTEM AT: [WWW.ECOMPLIANCE.KU.EDU](http://WWW.ECOMPLIANCE.KU.EDU)
3. IN THE "BASIC INFORMATION" SECTION OF THE SMART FORM, CHOOSE "KUMC" FOR ITEM #6 AND CHOOSE "YES" FOR ITEM #7. THE SYSTEM WILL AUTOMATICALLY SHORTEN THE REMAINDER OF THE APPLICATION QUESTIONS.
4. UNDER "SUPPORTING DOCUMENTS" UPLOAD THIS APPLICATION, THE ADMINISTRATIVE CERTIFICATION FROM YOUR DEPARTMENT CHAIR, THE STUDY PROTOCOL, DRUG INFORMATION, IF APPLICABLE, AND THE PROPOSED CONSENT FORMS AND RECRUITMENT MATERIALS IF THEY ARE AVAILABLE. YOU SHOULD ALSO INCLUDE ANCILLARY APPLICATIONS THAT MAY APPLY TO YOUR STUDY, SUCH AS RADIATION SAFETY, PRMC OR NURSING IMPACT.

**II. Study Personnel**

List the study team members from KUMC. In order for a research project to be approved, all members of the study team must demonstrate current training in human subjects protection. Study personnel also must have on file a current conflict of interest disclosure.



Name and Credentials (MD, PhD, RN, etc.)	Institution and Department	Role (PI, Co-I, Coordinator, etc.)	Responsibilities (see a – m below)
Brianna Kuster, RN	KU School of Nursing	PI	C, J, M
Dr. Karen Trees, DNP, RNC, CNM, WHCNP-BC, FNP-BC	KU School of Nursing	Coordinator	
Dr. Jill Peltzer, Ph.D., APRN-CNS	KU School of Nursing	Coordinator	

Please use corresponding letters for responsibilities. If not listed, record responsibility in box.

- |                                       |                                                             |
|---------------------------------------|-------------------------------------------------------------|
| a. Conduct informed consent interview | g. Take vital signs, height, weight                         |
| b. Complete physical examination      | h. Review/sign laboratory reports                           |
| c. Determine eligibility              | i. Draw/collect laboratory specimens                        |
| d. Review concomitant medications     | j. Perform tests, procedures, interventions, questionnaires |
| e. Complete study data forms          | k. Dispense/collect study medication                        |
| f. Determine causality of SAEs        | l. Complete drug accountability forms                       |
|                                       | m. Manage study database                                    |

### III. Determining the IRB of Record

Which institutions are taking part in this study? *(check all that apply)*

- ☒ Children's Mercy Hospital
- ☐ KCUMB
- ☐ St. Luke's Hospital
- ☐ Truman Medical Center
- ☒ University of Kansas Medical Center
- ☐ University of Missouri – Kansas City

At which institution will the most risky procedures occur? **Children's Mercy Hospital**

Where will the majority of study procedures take place? **Children's Mercy Hospital**

From which institution will the majority of subjects be recruited? **Children's Mercy Hospital**

At which institution will subjects spend the most time? **Children's Mercy Hospital**

### IV. Funding Information

- ☒ UNFUNDED: Check this box only if there will be no funding source for this project.
- ☐ SEEKING FUNDING from \_\_\_\_\_ (source)
- ☐ FUNDED
  - ☐ Pharmaceutical/Private Funds: \_\_\_\_\_
  - ☐ Federal Funds \_\_\_\_\_
  - ☐ Institutional Funds from \_\_\_\_\_
  - ☐ Other \_\_\_\_\_

### V. Conflict of Interest for All Study Team Members

Prior to HSC approval, an annual COI disclosure form must be on file for all KUMC study personnel. The following questions relate to the study named in this application.

**NOTE:** Principal Investigators are responsible for addressing these questions on behalf of the entire study team.

(a) ☐ Yes ☒ No Do any of the investigators or their immediate family\* have

financial arrangements with the sponsoring company or the products or services being evaluated, including:

- receipt of honoraria
- income, or
- stock/stock options

as payments in the past year or will be expected during the course of the project, that are:

- not publicly traded, or
- whose value may be affected by the outcome of the research?

*(\*Immediate family is defined as spouse, children, siblings, parents, equivalents by marriage [in-laws], or other household members)*

- (b) ☐ Yes ☒ No Do any investigators, study personnel, or their immediate family listed on this application have:
- consulting agreements
  - management responsibilities
  - ownership interests, or
  - equity holdings or options (regardless of value)
- in the sponsoring company, the providers of the products or services being evaluated, vendors, provider(s) of goods, or subcontractors?
- (c) ☐ Yes ☒ No Is any investigator, or their immediate family:
- a paid or unpaid member of an advisory or executive board, or
  - have a paid or unpaid executive relationship
- with the sponsoring company or the providers of the products or services being evaluated?
- (d) ☐ Yes ☒ No Do any investigators or their immediate family receive:
- gift funds
  - educational grants, or
  - subsidies or other remuneration
- from the sponsoring company?
- (e) ☐ Yes ☒ No Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?
- (f) ☐ Yes ☒ No Does KUMC or the KUMC Research Institute have an ownership or royalty interest in any intellectual property utilized in this protocol?
- (g) ☐ Yes ☐ No For drug/device studies only: is the sponsor of the study a different party than the manufacturer of the drug or device?
- (h) If you answered "Yes" to any of the above, please describe in detail. Affirmative answers will be forwarded to the KUMC Conflict of Interest Committee.

**Principle Investigator (Brianna Kuster) is employed as a RN in the Emergency Department at Children's Mercy Hospital**

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## VI. Study Procedures

Indicate whether this research project includes any of the following procedures.

- |                              |                                        |                                                                    |
|------------------------------|----------------------------------------|--------------------------------------------------------------------|
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | Use of Radiation                                                   |
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | Tests for HIV, Hepatitis, Tuberculosis or other reportable disease |
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | Testing for illegal drug use                                       |
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | Genetic Testing                                                    |
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | Storage of Blood/Tissue for purposes not related to this project   |
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | Recombinant DNA/ Gene Transfer                                     |
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | Invasive procedures                                                |
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | Inpatient stay                                                     |

## VII. Study Conduct at KUMC

Indicate which study procedures will occur at KUMC locations (check all that apply)

- ☐ All procedures outlined in the protocol,
- ☐ Subset of protocol procedures; Specify
- ☐ Recruitment
- ☐ Consenting
- ☒ Data analysis
- ☐ Data coordination
- ☐ Specimen analysis
- ☐ Other; Specify

## VIII. Drugs, Biologics, Devices

Please check all that apply:

- ☒ This study does not involve drugs, biologics or devices. *Proceed to Section IX.*
- ☐ This study involves vitamins, herbs, or supplements that are not regulated by FDA.
- ☐ This study involves **FDA-approved** drugs/drug combinations/biologics being used for the **FDA-approved indication** in the **FDA-approved population**.
- ☐ This study involves FDA-approved drugs, combinations or biologics being studied for an **unapproved use** (i.e., use is different from the FDA-approved indication and/or the FDA-approved population).
- ☐ This study involves **investigational** drugs, combinations, or biologics (i.e., not approved by FDA for any use).
- ☐ This study involves an **FDA-approved** device.
- ☐ This study involves an **investigational** device.

## IX. Pharmacy Information *(For Drug and Biologics only)*

Which pharmacy has overall responsibility for study drug accountability?

At which institutions will study drug be dispensed? *(check all that apply)*

- ☐ Children's Mercy Hospital
- ☐ KCUMB
- ☐ St. Luke's Hospital
- ☐ Truman Medical Center
- ☐ University of Kansas Medical Center
- ☐ University of Missouri – Kansas City

## X. Study Populations

Check all that apply to the target population for this study

- |                                                                 |                                                                |
|-----------------------------------------------------------------|----------------------------------------------------------------|
| <input type="checkbox"/> Healthy volunteers                     | <input type="checkbox"/> Adults 65 years and older             |
| <input type="checkbox"/> Patients                               | <input type="checkbox"/> Comatose/traumatized                  |
| <input type="checkbox"/> Children/Minors (under 7 years of age) | <input type="checkbox"/> Terminally ill                        |
| <input type="checkbox"/> Children/Minors (7 – 17 years of age)  | <input type="checkbox"/> Prisoners                             |
| <input type="checkbox"/> Pregnant women                         | <input type="checkbox"/> Homeless                              |
| <input type="checkbox"/> Fetuses/Neonates                       | <input type="checkbox"/> Persons w/ active psychiatric disease |
| <input type="checkbox"/> Cognitively impaired                   | <input checked="" type="checkbox"/> Site Employees             |
| <input type="checkbox"/> Males only                             | <input type="checkbox"/> Site Students/Residents/Fellows       |
| <input type="checkbox"/> Females only                           |                                                                |

## XI. Recruitment

How will subjects be identified? *(Check all that apply)*

- ☐ Selection during the course of usual clinical care
- ☐ Chart reviews by persons involved in the patients' care
- ☐ Chart reviews by persons not involved in the patients' care (such as study coordinators, data managers, students, research assistants, others who do not work in clinic)
- ☐ Self-referral in response to IRB-approved ads or Web-sites
- ☐ Referrals from outside physicians
- ☐ Database searches; specify the database:
- ☒ Other Physicians and APRNs that provide patient care at a Children's Mercy Hospital Urgent Care will be invited to answer the survey.

## XII. Data Security

At which institutions will identifiable study data or specimens be stored?

*(check all that apply)*

- ☒ Children's Mercy Hospital
- ☐ KCUMB
- ☐ St. Luke's Hospital
- ☐ Truman Medical Center
- ☒ University of Kansas Medical Center
- ☐ University of Missouri – Kansas City

**How will paper records be secured?**

**N/A**

**How will electronic records be secured?**

**REDCap**

**How will biospecimens be secured?**

**N/A**

### **XIII. Compliance Monitoring**

Which entity is responsible for monitoring the study to ensure protocol compliance?

- ☐ Sponsor/CRO
- ☐ Data Coordinating Center; Specify
- ☒ KUMC Study Team
- ☒ Other; Specify Children's Mercy Hospital

**Thank you for your submission. Please feel free to contact the IRB office with questions:**  
 (913) 588-1240 or [humansubjects@kumc.edu](mailto:humansubjects@kumc.edu)



## Appendix D

### Provider Survey

<p><b>Please select which best describes your role and educational preparation as a healthcare provider</b></p> <p><i>* must provide value</i></p>	<input type="radio"/> PNP <input type="radio"/> FNP <input type="radio"/> Physician <input type="radio"/> Moonlighter Physician <input type="radio"/> Moonlighter APRN
<p><b>Please select the range that best describes the number of years in practice as a healthcare provider:</b></p> <p><i>* must provide value</i></p>	<input type="radio"/> 0-3 <input type="radio"/> 4-6 <input type="radio"/> 7-10 <input type="radio"/> 11+
<p><b>Please Indicate the Urgent Care where you primarily practice:</b></p> <p><i>* must provide value</i></p>	<input type="radio"/> Children's Mercy Blue Valley <input type="radio"/> Children's Mercy East <input type="radio"/> Children's Mercy North <input type="radio"/> Float

---

**Please select the answer that best describes how you would treat the following patient:**

**What treatment would you recommend for the following patient: Previously healthy 3-year-old with a low-grade fever. On exam you see a gray, opaque, mildly bulging tympanic membrane with clear fluid noted behind the tympanic membrane.**

*\* must provide value*

☐ No Antibiotic  
☐ Antimicrobial therapy  
☐ Antihistamines and/or decongestants  
☐ Intranasal steroids

---

**Which of the following signs/symptoms would be used to document an otitis media with effusion? Select all that apply:**

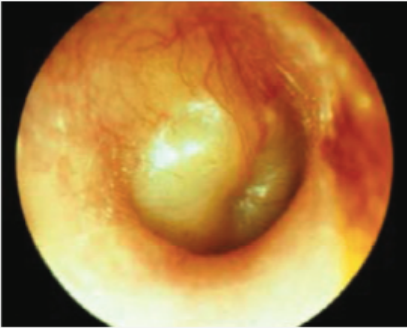
*\* must provide value*

☐ Lack of bulging tympanic membrane  
☐ Middle ear effusion  
☐ Bulging tympanic membrane  
☐ Mild erythema  
☐ Moderate erythema  
☐ Low-grade or no fever  
☐ Other: Please specify

**Please specify**

---

**Please view the following three images and select the most appropriate choice:**



**How would you label the above image of the middle ear?**

*\* must provide value*

☐ AOM  
☐ OME

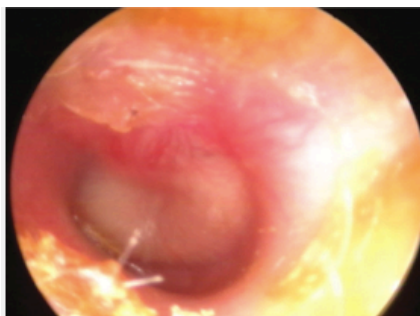


How would you label the above image of the middle ear?

☐ AOM

☐ OME

\* must provide value



How would you label the above image of the middle ear?

☐ AOM

☐ OME

\* must provide value

How likely are the following factors to influence your decision for diagnosing and treating OME outside the clinical practice guidelines?

	No likelihood	Low likelihood	Somewhat likely	Very likely
Parental pressure during patient encounter * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Professional experience * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Risk and liability of mis-diagnosis * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Parental satisfaction survey scores * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Do any other factors influence your decision for diagnosing and treating OME outside the clinical practice guidelines?

☐ Yes ☐ No

\* must provide value

Please specify

Have you reviewed the 2016 otitis media with effusion (OME) clinical practice guidelines co-developed by the American Academy of Otolaryngology-Head and Neck Surgery Foundation, the American Academy of Pediatrics, and the American Academy of Family Physicians?

☐ Yes ☐ No

\* must provide value

If so, do you follow the guidelines to treat OME?

☐ Yes ☐ No

Do you provide family education consistent with the 2016 guidelines for the diagnosis, treatment, and management of OME?

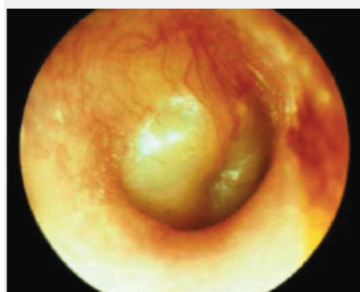
☐ Yes ☐ No

\* must provide value

What education do you provide?

What barriers prevent you from providing education?

Please describe what Cerner diagnosis or diagnoses you would select for each of the following three images:



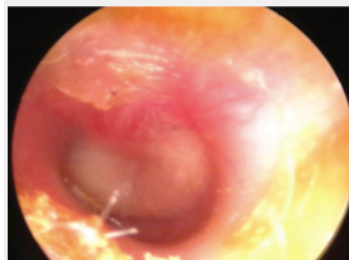
Using the Cerner diagnosis search box, what diagnosis or diagnoses would you select for the above image?

\* must provide value



Using the Cerner diagnosis search box, what diagnosis or diagnoses would you select for the above image?

\* must provide value



Using the Cerner diagnosis search box, what diagnosis or diagnoses would you select for the above image?

\* must provide value

*Note:* This survey was designed and developed by the researcher and implemented exclusively for the scholarly project.

## Appendix E

### Reminder Email

Dear UCC Provider,

My name is Brianna Kuster and I am an FNP-DNP student at KU. For my Capstone Project, I am conducting an antibiotic stewardship survey on otitis media, which I developed with the help of Donna Wyly APRN and Rana El Feghaly MD. Your completion of the survey will help determine potential quality improvement projects in the Urgent Cares.

**Please use the link below** to access a short survey for Urgent Care providers. This survey will take approximately 5-7 minutes to complete and all answers will remain completely anonymous. The survey will remain open until December 19th. Thank you in advance for your feedback!

If you have any questions about the survey, please contact me: [bnkuster@cmh.edu](mailto:bnkuster@cmh.edu). Thank you for taking the time to complete the survey.

**You may open the survey in your web browser by clicking the link below:**

[Survey of Prescribing Practices for Otitis Media with Effusion](#)

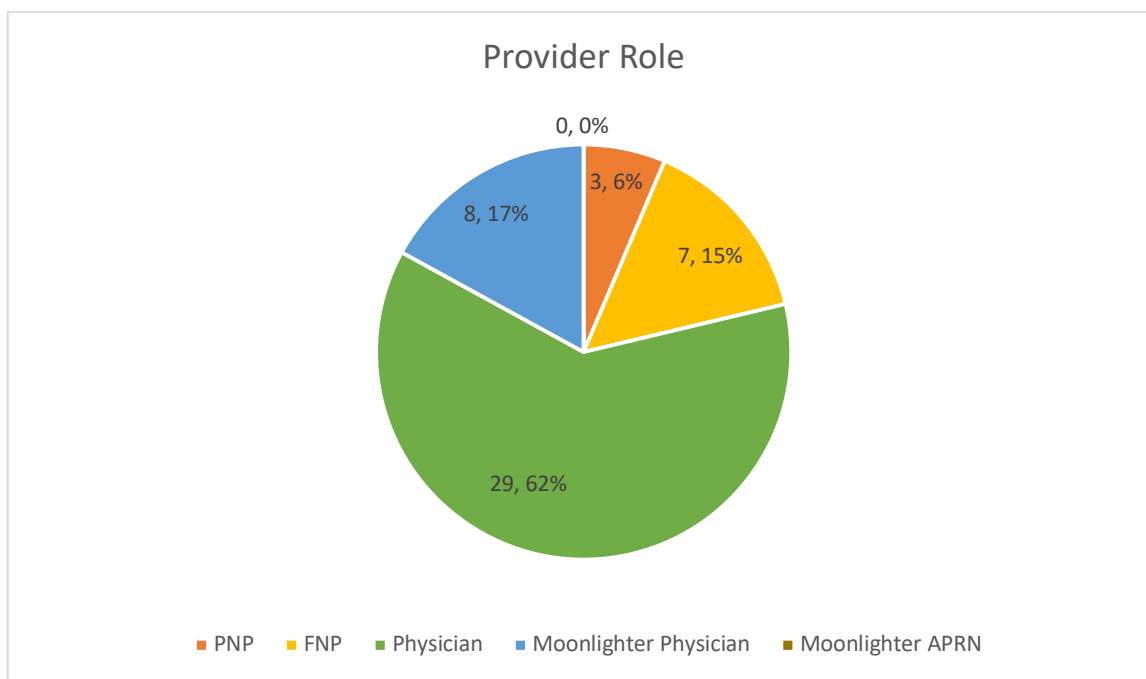
If the link above does not work, try copying the link below into your web browser:

<https://redcap.kumc.edu/surveys/?s=CWMLRNXXHL>

Thank you,  
Brianna Kuster, RN

## Appendix F

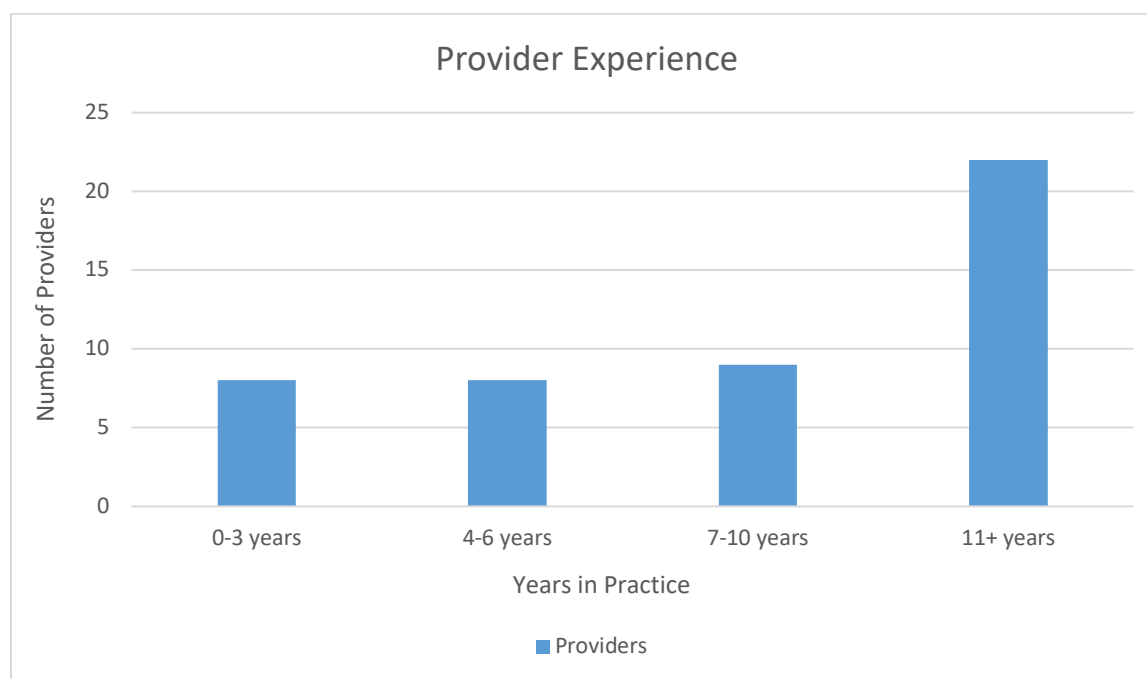
**Figure 1: Healthcare Provider Role**



*Figure 1:* This graph represents the question on the survey, “Please select which best describes your role and educational preparation as a healthcare provider.”

## Appendix G

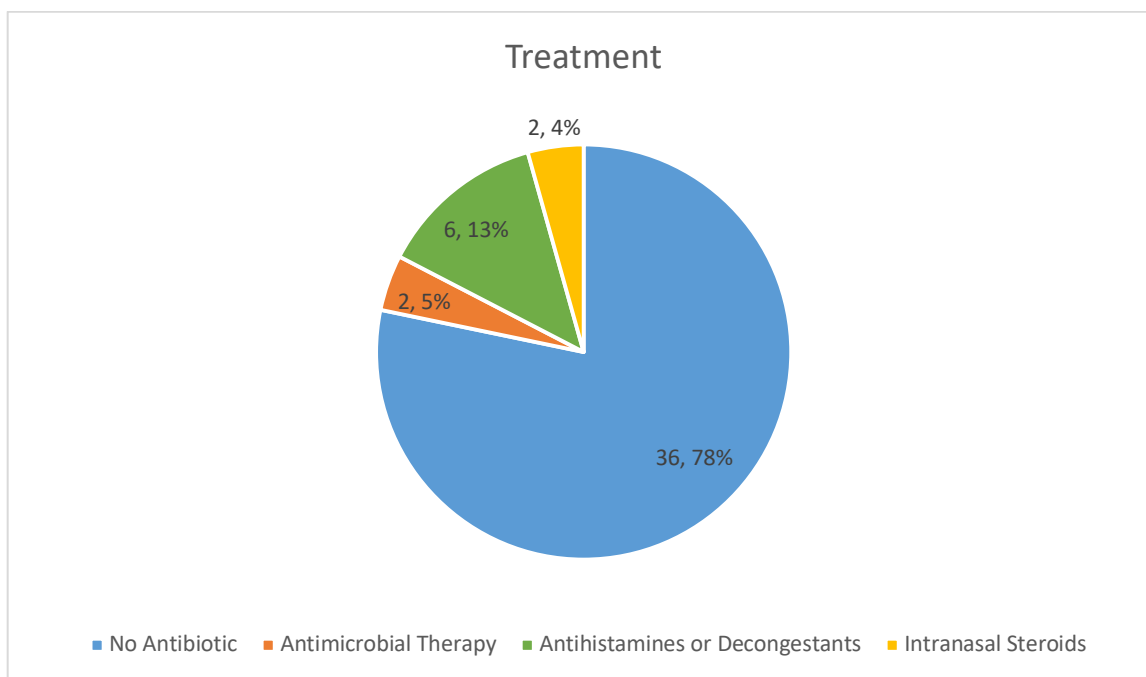
**Figure 2: Provider Years in Practice**



*Figure 2:* This graph represents the question on the survey, “Please select the range that best describes the number of years in practice as a healthcare provider.”

## Appendix H

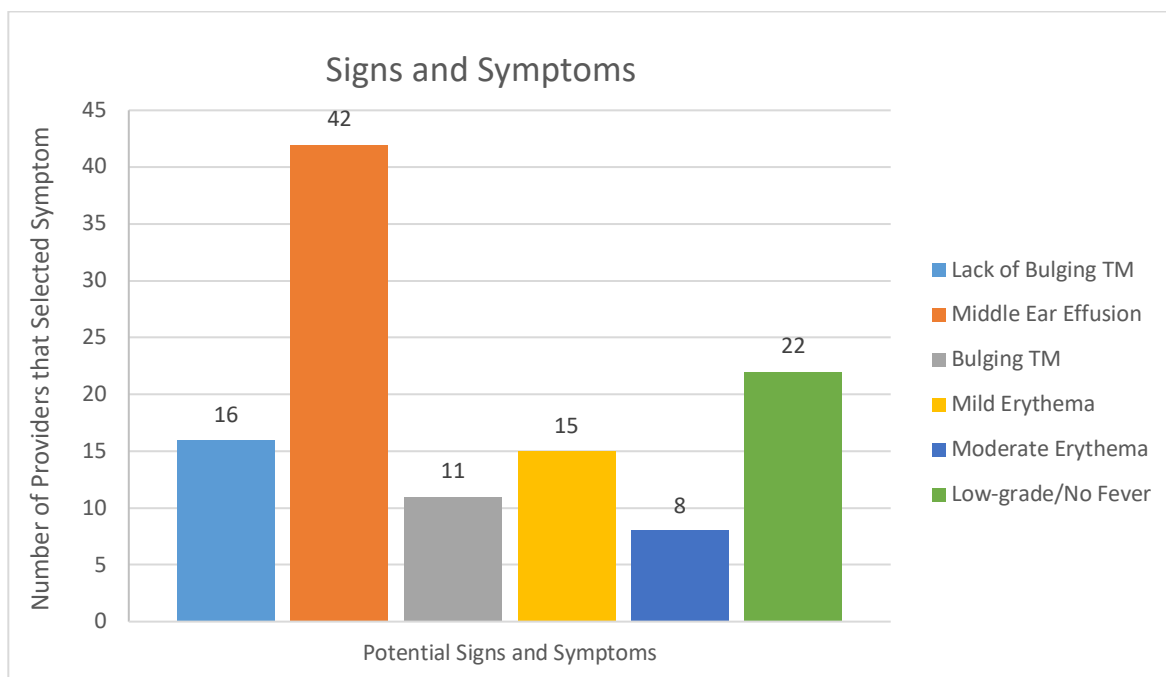
**Figure 3: OME Treatment Question**



*Figure 3:* This graph represents how providers answered the following question on the survey, “Please select the answer that best describes how you would treat the following patient: Previously healthy 3-year-old with a low-grade fever. On exam you see a gray, opaque, non-bulging or retracted tympanic membrane.”

## Appendix I

**Figure 4: OME Signs and Symptoms Question**

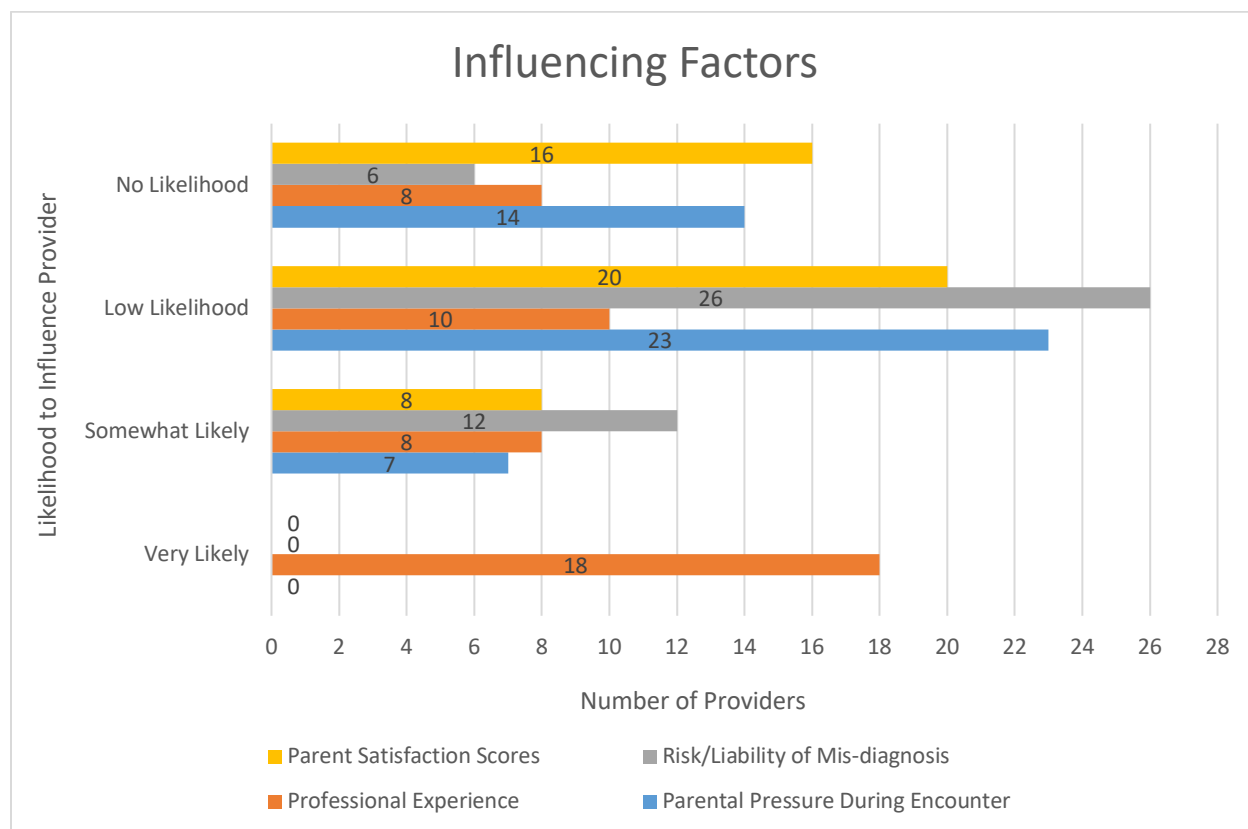


*Figure 4:* This graph represents how the providers answered the following question on the survey, “Which of the following signs/symptoms would be used to document an otitis media with effusion (OME)?”



## Appendix J

**Figure 5: Factors to Influence Diagnosis and/or Treatment Outside Clinical Guidelines**



*Figure 5:* This graph represents responses given on the following survey question, “How likely are the following factors to influence your decision for diagnosing and treating OME outside the clinical practice guidelines? Rank each of the following from 0-4. 0 = no likelihood, 1= low likelihood, 2 = somewhat likely, 3 = very likely.”